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TITLE: Increasing Treatment Seeking Among At-Risk Service Members Returning

from Warzones

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14. ABSTRACT

We propose a randomized controlled clinical trial of 1,200 military service members who are at increased risk for suicide but not currently in behavioral health treatment for the purpose of determining if a brief intervention improves the initiation of treatment. Participants assigned to the treatment condition will be presented an individualized CB intervention. The CB intervention takes 45-60 minutes, is delivered by phone, and has been shown to promote treatment-seeking including in a preliminary study of OEF/OIF Veterans with elevated posttraumatic stress disorder (PTSD) symptoms. Participants will be assessed at baseline and at 1-month, 3-month, and 6-month follow-up. Analyses are based on logistic and mixed effect models.

15. SUBJECT TERMS Nothing listed

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Abstract

Increasing Treatment Seeking Among At-Risk Service Members Returning from Warzones PI: Tracy Stecker, PhD, Co-PI: Kenneth Conner, PsyD

Background: Reducing suicide is a national priority and an urgent concern within the Department of Defense and the Department of Veterans Affairs. Indeed, rates of suicide among active duty service members have increased dramatically since 2005, and there is great concern that elevated risk will carry over following discharge from active service. The goal of the proposed study is to improve initiation of behavioral health (i.e., mental health, substance use) treatment services among untreated, at-risk U.S. military service members. The goal to facilitate behavioral health treatment is consistent with recommendations provided in reports by the Department of Defense, U.S. Army, U.S. Surgeon General, and the Institute of Medicine

Objective/Hypothesis:

Test the effectiveness of the intervention on attitudes toward behavioral health treatment among at-risk service members.

<u>Hypothesis 1a</u>: Participants receiving the cognitive-behavioral (CB) intervention will have significant increases in positive attitudes about treatment at 1-month follow-up compared to controls.

<u>Hypothesis 1b</u>: Participants receiving the CB intervention will have significant increases in the intention to initiate behavioral health treatment compared to controls.

Test the effectiveness of the intervention on the initiation of and adherence to behavioral health treatment.

<u>Hypothesis 2a</u>: Participants receiving the CB intervention will be more likely to initiate behavioral health treatment than participants in control group during 6-month follow-up. <u>Hypothesis 2b</u>: Participants receiving the CB intervention will attend more behavioral health treatment sessions than participants in the control group over 6-month follow-up.

Study Design: We propose a randomized controlled clinical trial of 1,200 military service members who are at increased risk for suicide but not currently in behavioral health treatment for the purpose of determining if a brief intervention improves the initiation of treatment. Participants assigned to the treatment condition will be presented an individualized CB intervention. The CB intervention takes 45-60 minutes, is delivered by phone, and has been shown to promote treatment-seeking including in a preliminary study of OEF/OIF Veterans with elevated posttraumatic stress disorder (PTSD) symptoms. Participants will be assessed at baseline and at 1-month, 3-month, and 6-month follow-up. Analyses are based on logistic and mixed effect models.

Relevance: Reducing suicide among our service members is a national priority. The passage of the Joshua Omvig Veterans Suicide Prevention Act highlights the importance that stakeholders place on developing and implementing a comprehensive program to reduce suicide among U.S. service members and Veterans.

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1. INTRODUCTION

Reducing suicide is a national priority and an urgent concern within the Department of Defense and the Department of Veterans Affairs. The passage of the Joshua Omvig Veterans Suicide Prevention Act highlights the importance that stakeholders place on developing and implementing a comprehensive program to reduce suicide among U.S. service members and Veterans. Rates of suicide among active duty service members have increased dramatically since 2005, and there is great concern that elevated risk will carry over following discharge from active service. *The goal of this study is to improve initiation of behavioral health (i.e., mental health, substance use) treatment services among untreated, at-risk U.S. military service members.* The goal to facilitate behavioral health treatment is consistent with recommendations provided in reports by the Department of Defense, U.S. Army, U.S. Surgeon General, and the Institute of Medicine.

We are conducting a randomized controlled clinical trial of 1,200 military service members who are at increased risk for suicide but not currently in behavioral health treatment for the purpose of determining if a brief intervention improves attitudes toward behavioral health treatment and initiation of treatment. Advertisements are used to recruit service members who report current suicidal ideation or a history of suicide attempt on standard screening items, suggesting they are at risk for suicide. Participants assigned to the treatment condition are presented an individualized cognitive-behavioral (CB) intervention. The CB intervention takes 45-60 minutes, is delivered by phone, and has been shown to promote treatment-seeking including in a preliminary study of OEF/OIF Veterans with elevated posttraumatic stress disorder (PTSD) symptoms. Participants are assessed at baseline and at 1-month, 3-month, 6-month, and 12-month follow-up. Analyses are based on logistic and mixed effect models. **Specific Aims are as follows**:

- Test the effectiveness of the intervention on attitudes toward behavioral health treatment among at-risk service members.
 <u>Hypothesis 1a</u>: Participants receiving the CB intervention will have significant increases in positive attitudes about treatment at 1-month follow-up compared to controls.
 <u>Hypothesis 1b</u>: Participants receiving the CB intervention will have significant increases in the intention to initiate behavioral health treatment compared to controls.
- 2) Test the effectiveness of the intervention on the initiation of and adherence to behavioral health treatment.
 <u>Hypothesis 2a</u>: Participants receiving the CB intervention will be more likely to initiate behavioral health treatment than participants in control group during 6-month follow-up.
 <u>Hypothesis 2b</u>: Participants receiving the CB intervention will attend more behavioral health treatment sessions than participants in the control group over 6-month follow-up.

The brief (45-60 min), practical (delivered by phone), and promising nature of the CB intervention (favorable preliminary data in OEF/OIF Veterans with elevated PTSD symptoms) indicate its potential for wider implementation to reduce suicide risk among service members.

2. KEYWORDS

Suicide, mental health treatment engagement, cognitive-behavioral intervention

3. OVERALL PROJECT SUMMARY

Recruitment for this trial began on March 2, 2013. We aimed to recruit approximately 250 individuals during each year of the trial, and have 788 participants as of February 2017. Of the 788 participants, 651 of them are separated from the service, 109 are active in the National Guard or Reserves, and 28 are Active Duty.

Baseline characteristics.

Characteristics of the participant sample that have been entered into the data management system are presented in Table 1 in the Appendix. The mean age of participants is approximately 31 years old, and 90% of the sample is male. The majority of participants identify their race as white, non-Hispanic. The vast majority reported service in the Army. Baseline symptom severity scores indicate that both the intervention and control groups reported moderately severe symptoms of depression (mean score = 18) as measured by the PHQ9 and PTSD (mean score = 62) as measured by the PCL.

Forty-two percent of the sample reported a previous suicide attempt during the baseline assessment. The majority of the attempts involved the use of medications and or alcohol. Overdosing on medications is also the most frequently reported method when asked if they have a plan for suicide. Other reported methods involve guns, cutting, car accidents, and carbon monoxide poisoning.

We have had four participants die during the trial. One participant died from heart failure related to the use of fentanyl, three died as a result of drug overdose. One of these overdoses was categorized as a suicide. All of these outcomes were reported to all IRB's involved and were judged to be unrelated to study participation.

No SAE's have occurred during this trial period.

Study Activities

In June 2016, this award was transferred from Dartmouth Medical School to the Medical University of South Carolina with the PI. At that point all recruitment and study activities ceased. As of February 2017, the award had not yet arrived to MUSC. Study activities will recommence when the award arrives at MUSC.

4. RESEARCH KEY ACCOMPLISHMENTS

• We have recruited 788 participants as of February 2017. Of the 788 participants, 651 of them are separated from the service, 109 are active in the National Guard or Reserves, and 28 are Active Duty. Of these, 373 have completed the trial.

5. CONCLUSION

Nothing to report.

6. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS

Publications

We have had the following two manuscripts published in peer reviewed journals. Several manuscripts are in preparation.

- **1.** Allan, N. P., Conner, K. R., Pigeon, W. R., Gros, D. F., Salami, T. K., & Stecker, T. (2017)Mar 8;252:296-302. Insomnia and suicidal ideation and behaviors in former and current U.S. service members: Does depression mediate the relations? *Psychiatry Research*.
- **2.** Allan NP, Gros DF, Hom MA, Joiner TE, Stecker T. (2016) Fall;79(3):249-261. Suicidal Ideation and Interpersonal Needs: Factor Structure of a Short Version of the Interpersonal Needs Questionnaire in an At-Risk Military Sample. *Psychiatry*.
- **3.** Gros, D. F., Silva, C., Allan, N. P., Lancaster, C. L., Conner, K. R., & Stecker, T. Relations between thwarted belongingness, perceived burdensomeness, and acquired capability and readiness for mental health treatment in high risk veterans. Revise and Resubmit.

Presentations

- 1. Stecker: Increasing Treatment Seeking Among Suicidal Military Members. HSRD VA Conference, February 2014
- 2. Stecker: Increasing Treatment Seeking Among Suicidal Military Members. Psychiatric Research Center, Dartmouth Medical School, March 2014
- 3. Stecker: Increasing Treatment Seeking Among Suicidal Veterans. VA cyberseries, September 2015
- 4. Stecker: Increasing Treatment Seeking Among Suicidal Military Members. Ralph H Johnson VA Grand Rounds, September 2015
- 5. Stecker: Increasing Treatment Seeking Among Suicidal Military Members. Ralph H Johnson VA COIN presentation, September 2015
- 6. Allan, N. Insomnia and suicidal ideation and behaviors in former and current U.S. service members: Does depression mediate the relations? Annual Anxiety and Depression Association of America conference, San Francisco, CA, April 2017
- 7. Saulnier, K. Suicidal ideation in high-risk veterans: Using growth mixture modeling to identify heterogeneous trajectories. Annual Anxiety and Depression Association of America conference, San Francisco, CA. April 2017

7. INVENTIONS, PATENTS, AND LICENSES

Nothing to report.

8. REPORTABLE OUTCOMES

Nothing to report.

9. OTHER ACHIEVEMENTS

We will recommence with study activities and recruitment as study staff are hired at MUSC by May 2017. Additionally we will have a particular focus on recruitment of active duty personnel and females.

10. REFERENCES

None

11. APPENDIX

Table 1: Baseline characteristics of the sample

Characteristic		n Participants : 387)	Control Participants (n = 383)		
	n	%	n	%	
Male	346	89.4	344	89.8	
Female	41	10.6	39	10.2	
Ethnicity					
White, non-Hispanic	262	67.7	253	66.1	
White, Hispanic	26	6.7	35	9.1	
Black, non-Hispanic	47	12.1	40	10.4	
Black, Hispanic	4	1.0	2	.5	
Native American	5	1.3	9	2.3	
Asian/Pacific Islander	12	3.1	11	2.9	
Other/or mixed race/ethnicity	28	7.2	31	8.1	
Missing	3	.8	2	.5	
Branch of Service					
Army	265	68.5	271	70.8	
Navy	36	9.3	39	10.2	
Airforce	34	8.8	28	7.3	
Marine	69	17.8	57	14.9	
Coast Guard	0	0	1	0.3	
Refused	1	.3	0	0	
	Mean	Range	Mean	Range	
Age	31.47	21-58	31.08	21-67	
PHQ-9 score at Baseline	17.63	4-27	18.39	4-27	
PCL score at Baseline	61.74	18-85	62.09	21-85	

Table 2: Treatment at 1 month follow-up

Characteristic	Intervention Participants (n = 387)		Control Participants (n = 383)		
	n	%	n	%	
Scheduled appointment	89	23.0	72	18.8	
Attended treatment	58	15.0	28	7.3	
Number of sessions attended	Mean	Range	Mean	Range	
	2.6	0-23	1.89	1-6	

Increasing Treatment Seeking Among At-Risk Service Members Returning from Warzones HRPO Log No. A-17345 Suicide Prevention in a Combat Environment W81XWH-13-2-0032



PI: Tracy Stecker, PhD Org: Dartmouth Medical School Award Amount: \$2,275,479

Study/Product Aim(s)

<u>Aim</u>: Test the effectiveness of a cognitive-behavioral intervention on the initiation of and adherence to behavioral health treatment among military personnel at-risk for suicide. This aim will be accomplished by having participants explore thoughts of treatment seeking, thus reducing stigma. <u>Hypothesis 1</u>: Participants receiving the intervention will be more likely to initiate treatment than control group participants.

<u>Hypothesis 2</u>: Participants receiving the intervention will attend more treatment than control group participants during the six-month follow-up.

Approach

1,200 military personnel at-risk for suicide will be randomly assigned to intervention or usual care conditions to test the effectiveness of the intervention to improve treatment seeking.

Recruitment on track

 Transferring award to the Medical University of South Carolina

Accomplishment: Place a description of the latest scientific accomplishment here. Limit the comments to three lines or less to make them fit; be succinct. These comments are valuable since they show progress.

Timeline and Cost

Activities CY	13	14	15	16	17/18
Obtain IRB and HRPO approva					
Recruit study participants					
Administer interventions and interviews					
Analyze data for reports and publications					
Estimated Budget (\$K)	\$457,666	\$441,625	\$449,596	\$467,448	\$503,221

Updated: 7/5/2016

Goals/Milestones

CY13 Goal

☑ IRB approval and begin recruitment

CY14 - CY 16 Goals - Recruit

- □Conduct baseline assessments, interventions, FU interviews
- □Transfer award from Dartmouth to MUSC with PI

CY17 Goal – Wrap up recruitment

□Organize study deliverables

Comments/Challenges/Issues/Concerns

- · Recruitment occurring as planned.
- · Assessments, interventions, FU interviews in progress as planned.

Budget Expenditure to Date

Projected Expenditure:

- Year 1 (3/2013-2/2014): \$457,666
- Year 2 (3/2014-2/2015): \$441,625
- Year 3 (3/2015- 2/2016): \$449,596
- Year 4 (3/2016-2/2017): \$467,448

Actual Expenditure:

- Year 1 (3/2013-2/2014): \$414,339
- Year 2 (3/2014-2/2015): \$457,572
- Year 3 (3/2015-2/2016): \$449,596